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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|------------------------------------------------------------|-------------|----------------------|---------------------|------------------|
| 10/764,371 | 01/23/2004 | Arnold Stan Lippa | 10596-018-999 | 9973 |
| 20583 | 7590 | 09/21/2004 | EXAMINER | |
| JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017 | | | | SOLOLA, TAOFIQ A |
| ART UNIT | | PAPER NUMBER | | |
| | | 1626 | | |

DATE MAILED: 09/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|-------------------------------------|-------------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/764,371 | LIPPA ET AL. | |
| | Examiner Taofiq A. Solola | Art Unit 1626 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
 THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 25,30 and 45-48 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
 5) Claim(s) ____ is/are allowed.
 6) Claim(s) 25,30,45-48
 is/are rejected.
 7) Claim(s) ____ is/are objected to.
 8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

Claims 25, 30, 45-48 are pending in this application.

Claims 1-24, 26-29, 31-44, 49-56 are cancelled.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 30, 45-48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to treating or preventing an addictive disorder arising through any mechanism. However, the specification disclosure is limited to addictive disorder arising from inhibition of dopamine reuptake. Also, the only assay in the specification relates to the affinity of the instant compound for dopamine receptor. No assay was performed to determine if co administration of the instant compound would lead to partial or complete blockage of the addictive effect of food, alcohol, nicotine, amphetamine, cannabis, cocaine, hallucinogens, inhalants or opioid. Therefore, the specification lacks adequate support for the claims.

Applicant must show possession of the invention by describing it with all the claimed limitations.

Lookwood v. American Airlines Inc. 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed Cir. 1997).

On page 3, last paragraph, the specification recites references that demonstrated co administration of “certain pharmaceutical agents” leads to partial blockage of the effects of the

agents. These were incorporated by reference on the last page of the specification. First, the agents are not taught to be the same as the instant compound. Second, such incorporation by reference is not in accordance with the requirement of the MPEP, which states as follows:

A mere reference to another application, publication or patent is not an incorporation of anything therein into the application containing such reference for the purpose of satisfying the requirement of 35 USC 112, first paragraph. *In re de Seversky*, 474 F.2d 671, 177 USPQ 144 (CCPA 1973). Particular attention should be directed to specific portions of the referenced document where the subject matter being incorporated may be found. MPEP 608.01(p).

If the document is a pending US application: prior to allowance of an application that incorporates essential material by reference to a pending US application, if the referenced application has not been published or issued as a patent, applicant is required to amend the disclosure of the referencing application to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating the amendment consists of the same material incorporated by reference in the referencing application. MPEP 608.01(p).

Claims 30, 45-48 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for inhibition of dopamine reuptake, does not reasonably provide enablement for all the various mechanisms giving rise to addictive disorder or the individual addictive disorders listed in claim 30. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. The claimed methods of use are not believable on their face.

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For rejection under 35 U.S.C. 112, first paragraph, the following factors must be considered (In re Wands, 8 USPQ2d 1400, 1404 (CAFC, 1988)):

- 1) Breadth of claims.
- 2) Nature of invention.
- 3) State of prior art.
- 4) Level of ordinary skill in the art.
- 5) Level predictability in the art.
- 6) Amount of direction and guidance provided by the inventor.
- 7) Existence of working examples.
- 8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The breath of the claimed invention involves medicinal chemistry. The nature of the invention is in the field of using the compound for treating addictive disorders due to any mechanism in the body and specific disorders listed in claim 30. The state of the prior art is what prior art knows about the nature of the invention. There is no known prior art claiming the use of compounds for treating the addictive disorder arising from any and/or all mechanisms. The level of ordinary skill in the art is high but only in treating specific addictive disorder having specific mechanism with specific compound. The predictability or lack thereof in the art refers to the ability of one skilled in the art to extrapolate the disclosed or known results to the claimed invention. The lower the predictability, the higher the direction and guidance that must be provided by applicant. In the instant invention the predictability is very low and consequently, the need for higher levels of direction and guidance by applicant. However, the amount of direction and guidance provided by applicant is limited to assay on the affinity of the instant compound for dopamine receptor site. There is a very large variety of sources for the listed

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disorders because different mechanisms are involved. It is well known in the art that the mechanism of a specific disorder would dictate the choice of treatment compound. Additionally, there is no evidence in the specification that established correlation between applicant experiment and all the possible mechanisms giving rise to addictive disorders. See Ex parte Mass, 9 USPQ2d 1746, 1987. Therefore, the quantity of experimentation required to use the compound as claimed, based on applicant's limited disclosure would be undue burden because, one of ordinary skill in the art would have to perform significant amount of experiments. By limiting the addictive disorder to those whose mechanisms have support in the specification the rejection would be overcome.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 25, 30, 45-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beer et al., US 6,204,284 B1.

Applicant claims a method of using the instant compound for treating addictive disorder. In preferred embodiment the compound is in its (-) isomeric form substantially free of the corresponding enantiomer.

Determination of the scope and content of the prior art (MPEP §2141.01

Beer et al., teach a method of using the racemic mixture of the instant compound for treating addictive disorder.

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Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant invention and that of Beer et al., is that applicant uses the (-) isomer substantially free of the corresponding enantiomer instead of racemic mixture by Beer et al.

Finding of prima facie obviousness--rational and motivation (MPEP §2142.2413)

However, the racemic mixture of Beer et al., include the (-) isomer and the phraseology "substantially free" implies the instant compound is not 100 % (-) isomers. The compound of Beer et al., and the instant compound have both isomers except in degrees. Therefore, the instant invention is *prima facie* obvious from the teaching of Beer et al. One of ordinary skill in the art would have known to use the (-) isomer at the time the invention was made. The motivation is from a well-established principle that an isomer is sometimes more reactive than the corresponding isomer or the racemate. *In re Adamson*, 125 USPQ 233 (1960).

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taofiq A. Solola, PhD, JD, whose telephone number is (571) 272-0709.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph McKane, can be reached on (571) 272-0699. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.


TAOFIQ SOLOLA
PRIMARY EXAMINER

Group 1626

September 15, 2004